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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Naoko TSUJI, et al.

GAU: 1651

SERIAL NO: 09/220,691

EXAMINER: WEBER

FILED: DECEMBER 28, 1998

FOR: METHOD OF INHIBITING HAIR GROWTH

REQUEST FOR PRIORITY

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

- ☐ Full benefit of the filing date of U.S. Application Serial Number, filed, is claimed pursuant to the provisions of **35 U.S.C. §120.**
- ☐ Full benefit of the filing date of U.S. Provisional Application Serial Number, filed, is claimed pursuant to the provisions of **35 U.S.C. §119(e).**
- ☒ Applicants claim any right to priority from any earlier filed applications to which they may be entitled pursuant to the provisions of **35 U.S.C. §119**, as noted below.

In the matter of the above-identified application for patent, notice is hereby given that the applicants claim as priority:

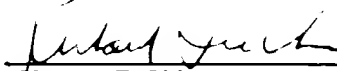
<u>COUNTRY</u>	<u>APPLICATION NUMBER</u>	<u>MONTH/DAY/YEAR</u>
JAPAN	10-005959	JANUARY/14/1998

Certified copies of the corresponding Convention Application(s)

- ☐ are submitted herewith
- ☐ will be submitted prior to payment of the Final Fee
- ☒ was filed with this application, Serial No. 09/220,691, on 12/28/98
- ☐ were submitted to the International Bureau in PCT Application Number .  
Receipt of the certified copies by the International Bureau in a timely manner under PCT Rule 17.1(a) has been acknowledged as evidenced by the attached PCT/IB/304.
- ☐ (A) Application Serial No.(s) were filed in prior application Serial No. filed ; and  
(B) Application Serial No.(s)
  - ☐ are submitted herewith
  - ☐ will be submitted prior to payment of the Final Fee

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

  
\_\_\_\_\_  
Norman F. Oblon

Attorney of Record

Registration No. 24,618

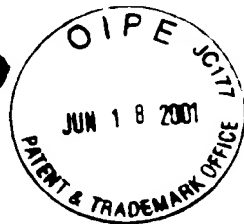
Richard L. Chinn, Ph.D.

Registration No. 34,305



22850

Tel: (703) 413-3000  
Fax: (703) 413-2220  
(OSMMN 10/98)



DECLARATION

I, Yoshiaki TODAKA of c/o TOKYO TECHNOPAT CORPORATION, 3-6, Nihonbashiningyocho 1-chome, Chuo-ku, Tokyo 103-0013 Japan do solemnly and sincerely declare that I well understand both Japanese and English languages and that I believe the attached English version is a true and complete translation of Japanese Patent Application No. 10-005959 filed on January 14, 1998 in the name of Kao Corporation.

May 25, 2001

*Yoshiaki Todaka*  
Yoshiaki TODAKA

*Yoshiaki Todaka*  
*May 25, 2001*

**PATENT OFFICE**  
**JAPANESE GOVERNMENT**

This is to certify that the annexed is a true copy of  
the following application as filed with this office.

Date of Application: January 14, 1998  
Application Number: Patent Application No. 10-005959  
Applicant(s): Kao Corporation

December 4, 1998

Takeshi ISAYAMA (Sealed)  
Commissioner,  
Patent Office

Hei 10-3098164

10-005959

[Document Name] APPLICATION FOR PATENT

[Reference Number] P00071001

[Filing Date] January 14, 1998

[Filed to] Commissioner, Patent Office

[International Classification] A61K 7/06

[Title of the Invention] METHOD OF INHIBITING HAIR GROWTH

[Number of Claims] 3

[Inventor]  
[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Naoko TSUJI

[Inventor]  
[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Shigeru MORIWAKI

[Inventor]  
[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Atsushi CHUCHI

[Inventor]  
[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Yoshinori TAKEMA

10-005959

[Inventor]

[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Yasuto SUZUKI

[Inventor]

[Domicile or Residence] c/o Kao Corporation, Resesarch  
Laboratories, 2606, Akabane,  
Ichikai-machi, Haga-gun, Tochigi  
[Name] Genji IMOKAWA

[Applicant for Patent]

[Identification Number] 000000918  
[Name] Kao Corporation

[Agent]

[Identification Number] 100068700  
[Patent Attorney]  
[Name] Mitsuyuki ARUGA

[Authorized Agent]

[Identification Number] 100077562  
[Patent Attorney]  
[Name] Toshio TAKANO

[Authorized Agent]

[Identification Number] 100096736  
[Patent Attorney]  
[Name] Toshio NAKAJIMA

[Authorized Agent]

[Identification Number] 100101317  
[Patent Attorney]  
[Name] Hiromi MATOBA

[Authorized Agent]

[Identification Number] 100101317  
[Patent Attorney]  
[Name] Sumio TANAI

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[List of Appended Documents]

[Document Name]	Specification	1
[Document Name]	Drawing	1
[Document Name]	Abstract	1

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[Request of Identification of Data]	Requested
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[Document Name] Specification

[Title of the Invention] METHOD OF INHIBITING HAIR GROWTH

[Claims]

[Claim 1] A hair-growth inhibitor comprising an inhibitor of elastase-like enzymes as an active ingredient.

[Claim 2] The hair-growth inhibitor according to Claim 1, wherein the inhibitor of elastase-like enzymes is an inhibitor of an elastase-like enzyme derived from a dermal fibroblast.

[Claim 3] The hair-growth inhibitor according to Claim 1 or 2, wherein the inhibitor is used in the form of an external skin-care composition.

[Detailed Description of the Invention]

[0001]

[Technical Field to which the Invention Belongs]

The present invention relates to a hair-growth inhibitor, and more particularly to a hair-growth inhibitor, by which hair growth on the legs and arms, and the like can be effectively inhibited.

[0002]

[Prior Art]

A biological function of the scalp hair and body hair is to protect important organs of the head, chest, limbs and the like. With the development of clothes and protecting means, however, the organ-protecting function carried by the body hair has come to be unimportant.

[0003]

The scalp hair is generally desired to be thick. In recent years, however, the tendency to prefer having no hair on, particularly, limbs and the like has been strengthened from the viewpoint of an aesthetic appearance. Therefore, various methods for removing the body hair have been developed and used. Specific examples thereof include mechanical removing methods making use of a shaver, hair plucker or the like, methods of using a depilatory to depilate body hair out of its root, methods of using a hair remover to remove body hair by its chemical reaction, etc.

[0004]

[Problems Sought for Solution by the Invention]

However, these methods for removing the body hair are accompanied by the physical or chemical irritation of the skin, and the lastingness of their removing effects on the body hair is limited even though there is some difference between the methods. Therefore, such a treatment for removing the body hair must be conducted again after a certain period of time. It is thus desired to lighten the removal treatment of the body hair.

[0005]

Accordingly, it is an object of the present invention to provide a hair-growth inhibitor by which the growth of body hair can be effectively inhibited to reduce the number of removal treatments of the body hair.

[0006]



[Means for the solution of the Problems]

In view of the foregoing circumstances, the present inventors have carried out an extensive investigation. As a result, it has been quite surprisingly found that inhibitors of enzymes which degrade elastin known as a structural protein in the artery, tendon, skin or the like have an excellent inhibitory effect on hair growth, thus leading to completion of the present invention.

[0007]

The present invention thus provides a hair-growth inhibitor comprising an inhibitor of elastase-like enzymes as an active ingredient.

[0008]

[Mode for Carrying out the Invention]

As the inhibitor of elastase-like enzymes useful in the practice of the present invention, is preferred an elastase inhibitor, particularly, an inhibitor of elastase-like enzymes derived from a dermal fibroblast. Such inhibitors include substances which exhibit an inhibitory activity of at least 50% at 1 mM in an enzyme activity-measuring system making use of an enzyme solution extracted from, for example, cultured human fibroblasts with a 0.1% Triton X-100/0.2 M Tris- hydrochloric acid buffer solution (pH: 8.0) and containing N-succinyl-Ala-Ala-Ala-p-nitroanilide as a substrate.

[0009]

Examples of such elastase-like enzyme inhibitors

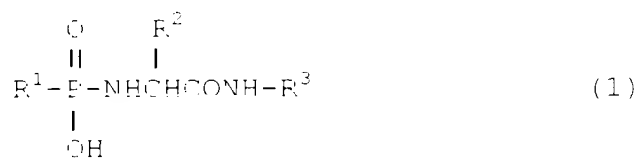
include phosphonic acid derivatives, mercaptopropionamide derivatives and salts thereof.

[0010]

The phosphonic acid derivatives include compounds represented by the following general formula (1):

[0011]

[Chemical Formula 1]



[0012]

wherein  $\text{R}^1$  is a hydrogen atom, a hydroxyl group, a hydrocarbon group which may be substituted, or a sugar residue which may be substituted,  $\text{R}^2$  is a hydrogen atom, a hydrocarbon group which may be substituted, or a sugar residue which may be substituted, and  $\text{R}^3$  is a hydrogen atom or a  $-\text{CH}(\text{R}^4)\text{COOH}$  (in which  $\text{R}^4$  is a hydrogen atom or a hydrocarbon group which may be substituted), and salts thereof.

[0013]

In the formula (1), the hydrocarbon groups which are represented by  $\text{R}^1$ ,  $\text{R}^2$  and  $\text{R}^4$  and may be substituted may be either saturated hydrocarbon groups or unsaturated hydrocarbon groups, and examples thereof include alkyl, alkenyl, alkynyl, cyclic alkyl, cyclic alkenyl, aromatic hydrocarbon and aralkyl groups. These hydrocarbon groups preferably have 1 to 24 carbon atoms, particularly 1 to 18

carbon atoms.

[0014]

Of the hydrocarbon groups, the alkyl, cyclic alkyl, aromatic hydrocarbon and aralkyl groups are preferred. The alkyl groups are preferably linear or branched alkyl groups having 1 to 12 carbon atoms, with n-propyl, isopropyl, n-butyl, isobutyl, tert-butyl and isoamyl groups being more preferred. The cyclic alkyl groups are preferably 5- to 7-membered alicyclic alkyl groups, with cyclopentyl and cyclohexyl group being more preferred. The aromatic hydrocarbon groups are preferably aromatic hydrocarbon groups having 6 to 14 carbon atoms, such as phenyl and naphthyl groups. The aralkyl groups are preferably alkyl groups having 1 to 5 carbon atoms, which have been substituted by an aromatic hydrocarbon group having 6 to 12 carbon atoms, and examples thereof include 2-phenylethyl (= phenethyl), 2-(1-naphthyl)ethyl and 2-(2-naphthyl)ethyl groups.

[0015]

Examples of atoms or groups which may be substituted on these hydrocarbon groups include halogen atoms, a hydroxyl group, alkoxyl groups, acyl groups, an amino group which may be protected, and heterocyclic groups. The halogen atoms include chlorine, bromine and iodine atoms. The alkoxyl groups are preferably alkoxyl groups having 1 to 12 carbon atoms, and examples thereof include methoxy, ethoxy and isopropoxy groups. The acyl groups

are preferably alkanoyl groups having 1 to 12 carbon atoms, and examples thereof include acetyl, propionyl and butyryl groups. Examples of the amino group which may be protected include amino, acylamino and alkylamino dialkylamino groups. The heterocyclic groups are preferably 5- to 14-membered monocyclic or fused ring groups having, as heteroatom(s), 1 to 3 nitrogen, oxygen and/or sulfur atoms, and examples thereof include pyridyl, pyridazinyl, furyl, thienyl, indolyl, thiazolyl, imidazolyl, benzofuryl and benzothienyl groups.

[0016]

The sugar residues include monosaccharide residues and oligosaccharide residues. Examples of groups which may be substituted on these sugar residues include alkyl, acyl and aralkyl groups. Examples of the alkyl, acyl and aralkyl groups include the same alkyl, acyl and aralkyl groups as mentioned above.

[0017]

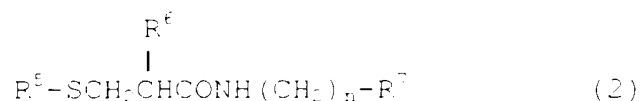
These phosphonic acid derivatives can be prepared in accordance with, for example, the process described in Japanese Patent Application Laid-Open No. 105698/1993.

[0018]

The mercaptopropionamide derivatives include, for examples, compounds represented by the following general formula (2):

[0019]

[Chemical Formula 2]



[0020]

wherein  $\text{R}^5$  is a hydrogen atom or an acyl group,  $\text{R}^6$  is a hydrogen atom or a hydrocarbon group which may be substituted,  $\text{R}^7$  is a hydrogen atom, a carboxyl group, an alkoxycarbonyl group, a hydrocarbon group which may be substituted, a heterocyclic group which may be substituted, or an acyl group, and  $n$  is a number of 1 to 20.

[0021]

In the formula (2), the acyl groups represented by  $\text{R}^5$  and  $\text{R}^7$  include alkanoyl groups and arylcarbonyl groups. The alkanoyl groups are preferably alkanoyl groups having 1 to 12 carbon atoms, and examples thereof include acetyl, propionyl and butyryl groups. The arylcarbonyl groups are preferably having 7 to 15 carbon atoms, and examples thereof include benzoyl, substituted benzoyl, naphthylcarbonyl and substituted naphthylcarbonyl groups. Examples of groups or atoms substituted on the benzoyl and naphthylcarbonyl groups include alkyl groups, alkoxyl groups, halogen atoms, an amino group, a hydroxyl group and alkanoyloxy groups.

[0022]

The hydrocarbon groups which are represented by  $\text{R}^6$  and  $\text{R}^7$  and may be substituted include the same groups as those mentioned above as to  $\text{R}^1$ ,  $\text{R}^2$  and  $\text{R}^4$ .

[0023]

The heterocyclic group represented by  $R^7$  is preferably a 5- to 14-membered monocyclic or fused ring group having, as heteroatom(s), 1 to 3 nitrogen, oxygen and/or sulfur atoms, and examples thereof include pyridyl, pyridazinyl, furyl, thienyl, indolyl, thiazolyl, imidazolyl, benzofuryl, benzothienyl, pyrrolidinyl, piperidinyl, morpholinyl and piperazinyl groups. Examples of atoms or groups which may be substituted on the heterocyclic group include halogen atoms, a hydroxyl group, alkoxyl groups, acyl groups and an amino group which may be protected. Specific examples of these substituents include the same substituents as the substituents of the hydrocarbon groups mentioned above as to  $R^1$ ,  $R^2$  and  $R^4$ .

[0024]

The alkoxycarbonyl group represented by  $R^7$  includes alkoxycarbonyl groups having 1 to 12 carbon atoms, and specific examples thereof include methoxycarbonyl, ethoxycarbonyl, isopropoxycarbonyl and butoxycarbonyl groups.

[0025]

These mercaptopropionamide derivatives can be prepared in accordance with, for example, the process described in Japanese Patent Application Laid-Open No. 24354/1982. Incidentally, these mercaptopropionamide derivatives are known to have an inhibitory effect on mammalian collagenases, but not known at all to have an inhibitory effect on elastase-like enzymes.

[0026]

The phosphonic acid derivatives and mercapto-propionamide derivatives may be used in the form of pharmaceutically acceptable salts or hydrates. Examples of the salts include alkali metal salts, alkaline earth metal salts, organic amine salts and amino acid salts. Examples of the alkali metal salts include the sodium salt and potassium salt. The examples of the alkaline earth metal salts include the calcium salt and magnesium salt. Examples of the organic amine salts include the ammonium salts, methylamine salt, triethylamine salt and pyridinium salt. Examples of the amino acid salts include the arginine salt, lysine salt and histidine salt. The alkali metal salts and amino acid salts are more preferred.

[0027]

No particular limitation is imposed on the hair-growth inhibitor according to the present invention. However, it is preferably used in the form of an external skin-care composition, particularly, a cosmetic composition related to hair removal, depilation or shaving. Specific examples of such a cosmetic composition include hair removers in the form of paste, cream or aerosol, depilatories in the form of wax, gel or sheet, after-treatment compositions used for a treatment after hair removal or depilation, such as lotion and cream, antiperspirant and deodorant cosmetics such as deodorant lotion, deodorant powder, deodorant spray and deodorant

stick, treatment compositions before shaving, such as pre-shave lotion, shaving compositions such as shaving cream, and treatment compositions after shaving, such as after-shave lotion.

[0028]

It is preferred that the amount of the active ingredient incorporated into the hair-growth inhibitor according to the present invention be generally 0.0001 to 10 % by weight, particularly, 0.001 to 3 % by weight from the viewpoints of the inhibitory effect on hair growth, profitability, etc.

[0029]

In the hair-growth inhibitor according to the present invention, various optional ingredients commonly used for cosmetics, quasi-drugs and drugs may be suitably incorporated as needed so far as no detrimental influence is thereby imposed on the effects of the present invention. Examples of such optional ingredients include purified water, ethanol, oily substances, moisturizers, thickeners, preservatives, emulsifiers, medicinally-effective agents, powders, ultraviolet absorbents, pigments, perfume bases and emulsion stabilizers.

[0030]

Examples of the oily substances include liquid paraffin, vaseline, paraffin wax, squalane, beeswax, carnauba wax, olive oil, lanolin, higher alcohols, synthetic esters of a higher alcohol and a fatty acid and



silicone oil. Examples of the moisturizers include sorbitol, xylitol, glycerol, mannitol, propylene glycol, 1,3-butylene glycol, 1,4-butylene glycol, sodium pyrrolidonecarboxylate, lactic acid, sodium lactate, polyoxyethylene fatty acid esters and polyethylene glycol. Examples of the thickeners include water-soluble polymers such as carboxyvinyl polymers, carboxymethyl cellulose, polyvinyl alcohol, carrageenan and gelatin, and electrolytes such as sodium chloride and potassium chloride. Examples of the preservatives include urea, methylparaben, ethylparaben, propylparaben, butylparaben and sodium benzoate. Examples of the emulsifiers include nonionic surfactants such as polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan fatty acid esters, glycerol fatty acid esters, polyglycerol fatty acid esters, polyoxyethylene glycerol fatty acid esters, polyoxyethylene hardened castor oil and polyoxyethylene sorbitol fatty acid esters. Examples of the powders include talc, sericite, mica, kaolin, silica, bentonite, vermiculite, zinc white, mica, mica titanium, titanium oxide, magnesium oxide, zirconium oxide, barium sulfate, iron oxide red, iron oxide and ultramarine blue.

[0031]

[Effects of the Invention]

The hair-growth inhibitors according to the present invention have an excellent inhibitory effect on hair growth and are high in safety for the human body.

[0032]

[Examples]

The present invention will hereinafter be described in more detail by the following Examples. However, the present invention is not limited to these examples.

[0033]

Example 1:

[Hair cycle and elastase activity]

After a fascia was removed from the shaved back skin of each of SD rats (male) aged 5 weeks to 13 weeks that were in various hair-growing stages, cutaneous tissue specimens 4 mm in diameter were prepared. A phosphate buffer solution (PBS) was then put in a peripheral part of a Petri dish for organ culture (Falcon 3037) for the purpose of keeping humidity constant, and the cutaneous tissue specimens (6 tissue specimens/dish) were arranged on a triangular grid placed on an inner dish with the epidermis upside. A liquid medium (DMEM, 0.7 ml) was added into the inner dish to conduct culture at 31°C for 24 hours in a gas phase of 60% O<sub>2</sub> and 5% CO<sub>2</sub>. The thus-obtained culture supernatant was used for the measurement of elastase activity.

[0034]

The measurement of elastase activity was conducted in accordance with the method by Bieth et al. [Biochem. Biophys. Res. Commun., 53, 383-390 (1973)]. More specifically, a 20 mM solution of N-suc-(Ala)<sub>3</sub>-p-

nitroanilide was used as a substrate and added in a proportion of 5  $\mu$ l per 95  $\mu$ l of the culture supernatant. A reaction was conducted at 37°C for 4 hours, and an absorbance at 410 nm was measured, thereby determining the amount of nitroaniline formed by the reaction with the enzyme. With respect to the enzyme activity, the activity that 1 nmol per hour of nitroaniline is formed was regarded as 1 unit.

[0035]

As apparent from the result shown in Fig. 1, the rise and fall of the activity of an elastase in the cutaneous tissue released in the culture supernatant very much corresponded to the hair cycle thereof. More specifically, a high value was exhibited in a hair follicle-forming phase (growth phase), and a fall in activity value was recognized in a transient phase or resting phase. This result suggests that a rise in the activity of the elastase in the cutaneous tissue is indispensable to hair follicle formation and its growth.

[0036]

Test Example 1: Elastase activity-inhibiting test in  
cultured human fibroblast

Normal human fibroblasts commercially available from Dainippon Pharmaceutical Co., Ltd. were subcultured in a DMEM medium containing a 10% fetal bovine serum and used in this test. The cells separated from a Petri dish with a rubber policeman were suspended in PBS, collected by

means of a low-speed centrifugal separator and washed 3 times with PBS. The thus-treated cells were suspended in a 0.1% Triton X-100/0.2 M Tris-HCl buffer (pH: 8.0) and ultrasonically disrupted to use as an enzyme solution.

125 mM N-Suc-(Ala)<sub>3</sub>-p-nitroanilide was used as a substrate for the measurement of enzyme activity, and each subject (1  $\mu$ l; its concentration is shown in Table 1) was added to the enzyme solution (100  $\mu$ l) to conduct a reaction at 37°C for 1 hour. The reaction was stopped by adding acetic acid (5  $\mu$ l). The amount of nitroaniline formed was determined by measuring an absorbance at 405 nm by means of a spectrophotometer. Percent inhibition of elastase activity by the subject is shown in Table 1.

[0037]

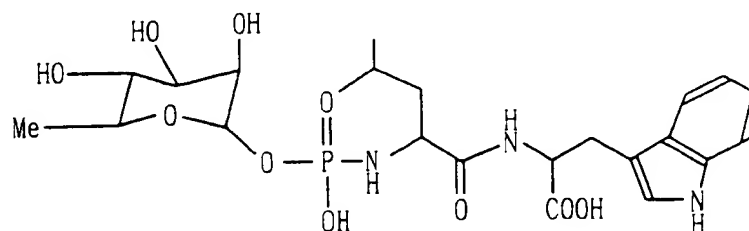
[Table 1]

Subject	Concentration	Percent inhibition of elastase activity (%)
Compound 1	0.1 mM	85.6
Compound 2	0.1 mM	82.1
Compound 3	0.1 mM	90.2
Compound 4	1 mM	68.4
Compound 5	0.1 mM	90.1
Compound 6	0.1 mM	88.7
Compound 7	0.1 mM	85.4

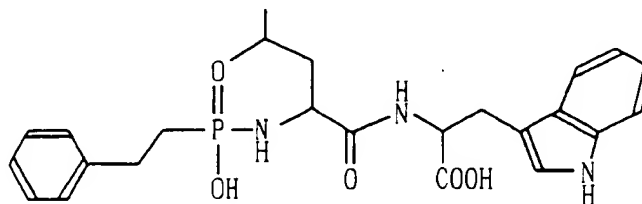
[0038]

[Chemical Formula 3]

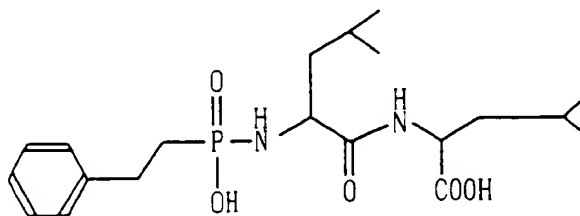
Compound 1:



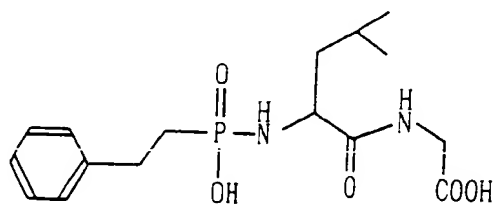
Compound 2:



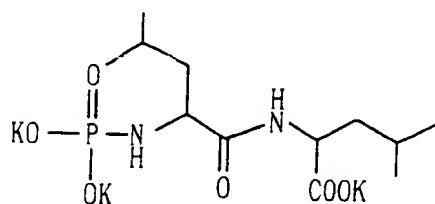
Compound 3:



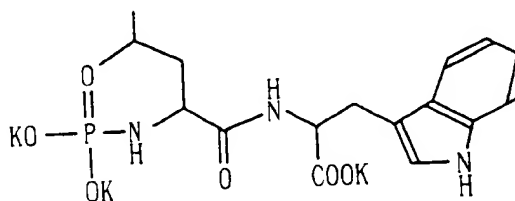
Compound 4:



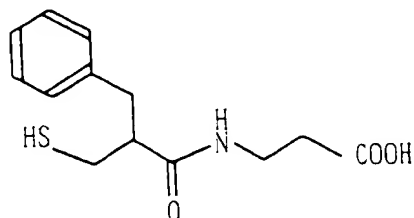
Compound 5:



Compound 6:



Compound 7:



Test Example 2: Test of inhibiting regeneration of mouse  
back hair

Back hair of a group of 5 C3H mice aged 6 weeks was shaved over  $2 \times 4 \text{ cm}^2$  by means of an electric hair clipper and an electric shaver so as not to damage their skins. Each subject was applied to the shaved sites twice a day in an amount of 100  $\mu\text{l}$ /time over 4 weeks. The subject was dissolved in a solvent (80% ethanol) to prepare a solution of a concentration shown in the following Table. Only the solvent was applied to a control group. After 3 weeks, a photograph of each shaved site was taken at a fixed magnification for observing the state of regenerated hair to compare a regenerated hair area ratio (regenerated hair area/shaved area) of the test group with that of the control group. The results are shown in Table 2.

[0040]

[Table 2]

Subject	Concentration	Percent inhibition of hair growth after 3 weeks from shaving (%)
Compound 1	1 mM	58.7
Compound 2	1 mM	59.1
Compound 3	1 mM	64.8
Compound 4	10 mM	60.5
Compound 5	1 mM	74.2
Compound 6	1 mM	62.1
Compound 7	1 mM	59.7

## [0041]

As apparent from Tables 1 and 2, the subjects, which are elastase inhibitors, had an excellent inhibitory effect on hair growth.

## [0042]

Example 2: Hair growth inhibiting lotion

	(wt.%)
A Polyoxyethylene hardened castor oil	0.8
Ethanol	30.0
B Compound 1	1.0
Sodium dodecylsulfate	0.12
Dodecylmethylanine oxide	0.18
Isopropyl alcohol	15.0
Benzyl alcohol	15.0
Glycerol	2.0
Purified water	Balance

## [0043]

The components belonging to A were dissolved, and the components belonging to B were separately dissolved. The solution of B was added to the solution of A to uniformly stir and mix both solutions, thereby obtaining a hair growth inhibiting lotion.

## [0044]

Example 3: Hair growth inhibiting cream

	(wt.%)
A Liquid paraffin	10.0
Squalane	7.0



Jocoba oil	3.0
Solid paraffin	3.0
Polyoxyethylene cetyl ether	2.0
Sorbitan sesquioleate	1.0
Potassium hydroxide	0.1
B Compound 1	1.0
Glycerol	3.0
Ethylparaben	0.1
Purified water	Balance

**[0045]**

The components belonging to A were heated to melt them, and the components belonging to B were separately heated to melt them. The melt of B was added to the melt of A to uniformly stir and mix both melts, thereby emulsifying them. The resultant emulsion was then cooled to obtain a hair growth inhibiting cream.

**[0046]**

Example 4: Hair growth inhibiting foam

	(wt.%)
A Compound 1	1.0
Cetanol	0.1
Propylene glycol	2.0
Dimethyl silicone oil	2.0
Polyoxyethylene hardened castor oil	2.5
Liquid paraffin	1.0
Polyvinyl pyrrolidone	0.5
Methylparaben	0.2

Ethanol	10.0
Purified water	Balance
B Liquefied petroleum gas (propellant)	4.0

[0047]

The components belonging to A were uniformly mixed and placed in a container. The component of B was charged into the container in accordance with a method known *per se* in the art to obtain a hair growth inhibiting foam.

[0048]

Example 5: Aerosol

	(wt.%)
A Compound 1	1.0
Cetanol	1.2
Propylene glycol	4.0
Ethanol	8.0
Purified water	Balance
B Liquefied petroleum gas (propellant)	4.0

[0049]

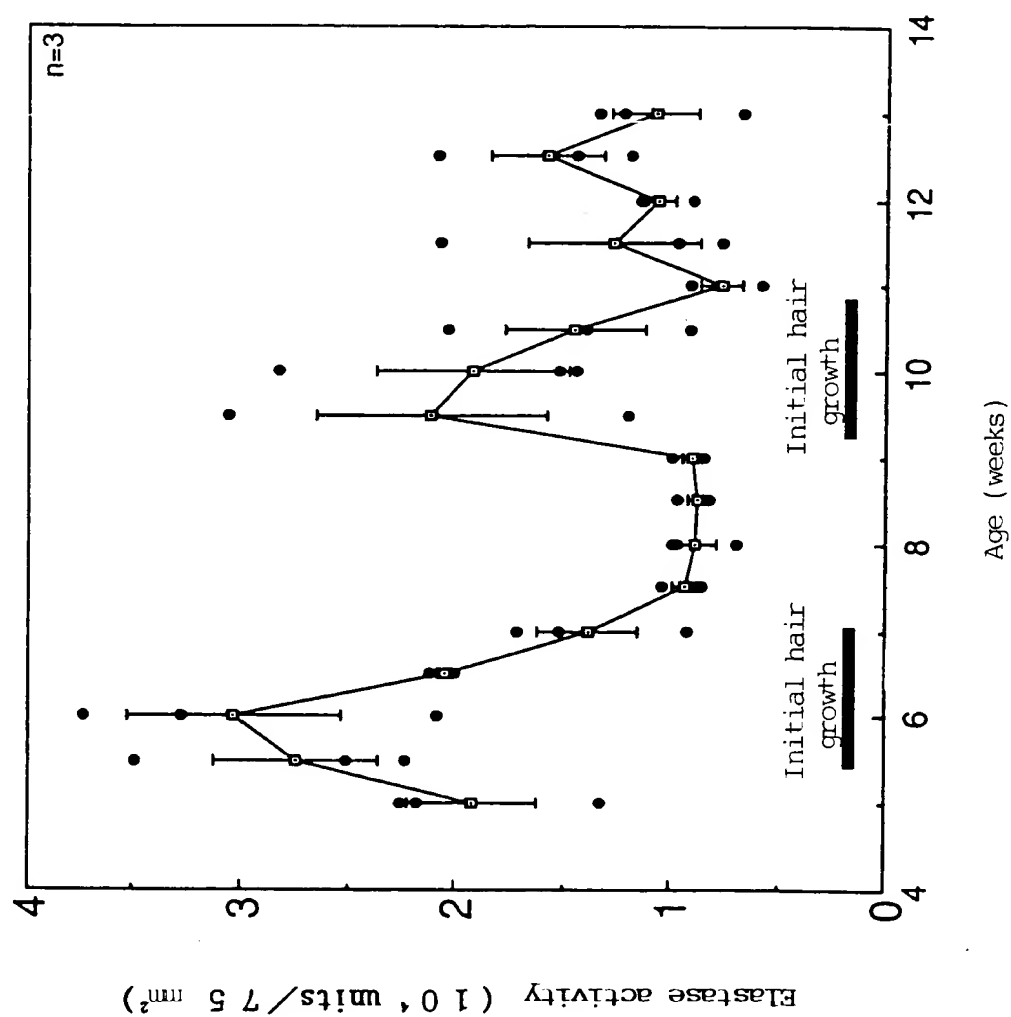
The components belonging to A were uniformly mixed and placed in a container. The component of B was charged into the container in accordance with a method known *per se* in the art to obtain an aerosol.

[Brief Description of the Drawing]

[Fig. 1]

The drawing diagrammatically illustrates the relationship between a hair cycle and the activity of an elastase in cutaneous tissue.

Fig. 1



1  
[Document Name] Abstract

[Abstract]

[Means for Solution] A hair-growth inhibitor comprising an inhibitor of elastase-like enzymes as an active ingredient.

[Effects] The inhibitor has an inhibitory effect on hair growth on the legs and arms.

[Selected Figure of Drawings] None

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【Document Name】 Data of Correction ex officio  
【Corrected Document】 Patent for Application

〈Recognized Information/Additional Information〉

【Applicant】

【Identification Number】 000000918  
【Domicile or Residence】 14-10, Nihonbashikayabacho 1-chome,  
Chuo-ku, Tokyo  
【Name】 Kao Corporation

【Agent】 PETITIONER

【Identification Number】 100077562  
【Domicile or Residence】 Kyodo Bldg., 3-6, Nihonbashiningyo cho  
1-chome, Chuo-ku, Tokyo  
【Name】 Mitsuyuki ARUGA

【Authorized Agent】

【Identification Number】 100077562  
【Domicile or Residence】 Aruga Patent Office  
Kyodo Bldg., 3-6, Nihonbashiningyo-cho  
1-chome, Chuo-ku, Tokyo  
【Name】 Toshio TAKANO

【Authorized Agent】

【Identification Number】 100077562  
【Domicile or Residence】 Aruga Patent Office  
Kyodo Bldg., 3-6, Nihonbashiningyo-cho  
1-chome, Chuo-ku, Tokyo  
【Name】 Toshio NAKAJIMA

【Authorized Agent】

【Identification Number】 100077562  
【Domicile or Residence】 Aruga Patent Office  
Kyodo Bldg., 3-6, Nihonbashiningyo-cho  
1-chome, Chuo-ku, Tokyo  
【Name】 Hiromi MATOBA

【Authorized Agent】

【Identification Number】 100106909  
【Domicile or Residence】 Aruga Patent Office  
Kyodo Bldg., 3-6, Nihonbashiningyo-cho  
1 chome, Chuo-ku, Tokyo  
【Name】 Sumio TANAI

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PERSONAL HISTORY OF APPLICANT

Identification Number [000000918]

1. Date of change August 24, 1990  
[Reason of change] New Registration  
Address: 14-10, Nihonbashikayabacho 1-chome,  
Chuo-ku, Tokyo  
Name: Kao Corporation